



PATENT
9694D-000002/US

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicants: Mitsuo FUKUDA et al. Conf. No.: 8672
Application No.: 10/784,877 Group No.: 3731
Filed: February 24, 2004 Examiner: Tyson, Melanie R.
For: MEDICAL LANCET

SUBMISSION OF THE ENGLISH LANGUAGE TRANSLATION OF FOREIGN
APPLICATION PURSUANT TO RULE 55 TO PERFECT CLAIM FOR PRIORITY UNDER
35 U.S.C. §119

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

October 17, 2007

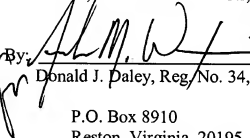
Sir:

Applicants hereby submit a certified English language translation of Japanese Patent Application No. 2003-422999 upon which the subject application claims priority.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

By:  #56,007
Donald J. Daley, Reg. No. 34,313

DJD/AMW:krm


P.O. Box 8910
Reston, Virginia 20195
(703) 668-8000

Attachments: Copy of Certified English Translation of JP 2003-422999



Verification of Translation

I, Takuji YAMADA, of c/o IMP Building, 1-3-7, Shiromi, Chuo-ku, Osaka 540-0001 Japan, hereby certify that I am conversant with the English and Japanese languages and further that, to the best of my knowledge and belief, the attached document is a true and correct translation made by me of the documents in the Japanese language attached hereto or identified as follows:

Japanese Patent Application No. 2003-422999
filed on December 19, 2003

Dated this 20th day of June, 2006

Takuji Yamada



PATENT OFFICE
JAPANESE GOVERNMENT

This is to certify that the annexed is a true copy of the following
application as filed with this Office.

Date of Application: December 19, 2003

Application Number : Patent Application No. 2003-422999

Applicant(s) : Lightnix, Inc.

February 10, 2004

Commissioner,
Patent Office

Yasuo IMAI (seal)



2003-422999

Document Name: Application for Patent

Docket No. : 191909

Date of Application: December 19, 2003

Addressee: Commissioner, Patent Office

International Patent

Classification: A61M 5/158

Inventor(s):

Address: 2-6, Kotoen 2-chome,
Nishinomiya-shi, Hyogo Prefecture
Name: Mitsuo FUKUDA

Address: 18-1-601, Yamate-cho 3-chome,
Suita-shi, Osaka Prefecture
Name: Seiji AOYAGI

Applicant:

Address: 2-6, Kotoen 2-chome,
Nishinomiya-shi, Hyogo Prefecture
Name: Lightnix, Inc.

Agent:

Identification No.: 100086405
Patent Attorney
Name: Osamu KAWAMIYA
Telephone No.: 06-6949-1261
Facsimile No.: 06-6949-0361

Appointed Agent:

Identification No.: 100101454
Patent Attorney
Name: Takuji YAMADA

2004-3008410

2003-422999

Telephone No.: 06-6949-1261

Facsimile No.: 06-6949-0361

Payment of Fees:

Prepayment Book No.:163028

Amount to be paid: 21,000 yen

Attached document:

Item:	Claims	1 copy
Item:	Specification	1 copy
Item:	Drawings	1 copy
Item:	Abstract	1 copy

2004-3008410

Applicant Record

Identification No.: 503467089

1. Date of Registration: December 19, 2003

Address: 2-6, Kotoen 2-chome,
Nishinomiya-shi, Hyogo Prefecture

Name: Lightnix, Inc.



PATENT OFFICE
JAPANESE GOVERNMENT

This is to certify that the annexed is a true copy of the following application as filed with this Office.

Date of Application: December 19, 2003

Application Number : Patent Application No. 2003-422999

Applicant(s) : Lightnix, Inc.

November 11, 2003

Commissioner,
Patent Office

Yasuo IMAI (seal)



2003-422999

Document Name: Application for Patent

Docket No. : 191909

Date of Application: December 19, 2003

Addressee: Commissioner, Patent Office

International Patent

Classification: A61M 5/158

Inventor(s):

Address: 2-6, Kotoen 2-chome
Nishinomiya-shi, Hyogo Prefecture
Name: Mitsuo FUKUDA

Address: 18-1-601, Yamate-cho
Suita-shi, Osaka Prefecture
Name: Seiji AOYAGI

Applicant:

Address: 2-6, Kotoen 2-chome
Nishinomiya-shi, Hyogo Prefecture
Name: Lightnix, Inc.

Agent:

Identification No.: 100086405
Patent Attorney
Name: Osamu KAWAMIYA
Telephone No.: 06-6949-1261
Facsimile No.: 06-6949-0361

Appointed Agent:

Identification No.: 100101454
Patent Attorney
Name: Takuji YAMADA

2003-3093138

2003-422999

Telephone No.: 06-6949-1261

Facsimile No.: 06-6949-0361

Payment of Fees:

Prepayment Book No.:163028

Amount to be paid: 21,000 yen

Attached document:

Item:	Claims	1 copy
Item:	Specification	1 copy
Item:	Drawings	1 copy
Item:	Abstract	1 copy

Request for Proof Transmission: Yes

2003-3093138

Applicant Record

Identification No.:

1. Date of Registration:

Address: 2-6, Kotoen 2-chome
Nishinomiya-shi, Hyogo Prefecture

Name: Lightnix, Inc.



[Document Name] CLAIMS

[Claim 1]

A medical lancet, comprising:

a first ascending region, a descending region, and a
5 second ascending region subsequently and integrally formed
of biodegradable material, extending from a point in a
predetermined direction, each of said regions having
triangular cross sections taken along any planes
perpendicular to the predetermined direction;

10 said first and second ascending regions having the
triangular cross sections of which area monotonically
increases as being away from the point; and

said descending region having the triangular cross
sections of which area monotonically decreases as being
15 away from the point;

wherein said first and second ascending regions have
the largest cross section having substantially the same
size and shape to each other.

[Claim 2]

20 The medical lancet according to Claim 1, further
comprising:

at least one additional descending and ascending
regions subsequently and integrally formed of biodegradable
material and connected to said second ascending region,
25 extending in the predetermined direction;

wherein each of said additional descending and ascending regions has the triangular cross sections taken along any planes perpendicular to the predetermined direction, of which area monotonically increases and decreases as being away from the point, respectively; and

wherein said first and second ascending regions have the largest cross section having substantially the same size and shape to each other.

[Claim 3]

The medical lancet according to Claim 1,

wherein the smallest cross section in the descending region is similar to the largest cross section in the ascending regions, and

wherein the smallest cross section in the descending region has the area greater than one-fourth of the area of the largest cross section in the ascending regions.

[Claim 4]

The medical lancet according to Claim 3,

wherein the smallest cross section in the descending region has the area greater than four-ninths of the area of the largest cross section in the ascending regions.

[Claim 5]

The medical lancet according to Claim 1,

wherein the largest cross sections in said first and second ascending regions are spaced away from each other by

a gap greater than one micron.

[Claim 6]

The medical lancet according to Claim 1,
wherein a continuous curved portion is provided
5 between said descending region and said second ascending
region for smoothly connecting thereof.

[Claim 7]

The medical lancet according to Claim 1, further
comprising:

10 a constant region integrally formed of biodegradable
material between said descending region and said second
ascending region, having triangular cross sections taken
along any planes perpendicular to the predetermined
direction, of which area is constant.

15 **[Claim 8]**

The medical lancet according to Claim 1,
wherein the area of the triangular cross sections in
the first and second ascending regions are linearly
increased at first and second increasing rates,
20 respectively, and the first increasing rate falling within
a range between one-sixteenth and one of the second
increasing rate.

[Claim 9]

The medical lancet according to Claim 8,
25 wherein the first increasing rate is one-ninth of the

second increasing rate.

[Claim 10]

The medical lancet according to Claim 1, further comprising:

- 5 a holding region of biodegradable material connected
to said second ascending region.

[Claim 11]

The medical lancet according to Claim 1, further comprising:

- 10 at least one channel extending in the predetermined
direction through at least one of said first and second
ascending regions and descending region.

[Claim 12]

- The medical lancet according to Claim 11,
15 wherein said holding region has at least one chamber
in communication with said channel.

[Claim 13]

The medical lancet according to Claim 12,
wherein said channel has at least one opening.

20 **[Claim 14]**

The medical lancet according to Claim 11,
wherein said channel has at least two openings spaced
away from each other by a predetermined gap.

[Claim 15]

- 25 The medical lancet according to Claim 11,

wherein a plurality of said channels are provided, and wherein said holding region has a plurality of said chambers, each of the chambers being in communication with corresponding one of said channels.

5 **[Claim 16]**

The medical lancet according to Claim 1, further comprising:

at least one groove extending in the predetermined direction through at least one of said first and second
10 ascending regions and descending region.

[Claim 17]

The medical lancet according to Claim 1, further comprising:

a plurality of vertical cavities extending in a
15 vertical direction perpendicular to the predetermined direction; and

a seal membrane of biodegradable material for sealing said vertical cavities;

wherein the seal membrane has the thickness in the
20 vertical direction varying based upon the position of each of the vertical cavities.

[Claim 18]

A medical lancet, comprising:

a first ascending region, a descending region, and a
25 second ascending region subsequently and integrally formed

of biodegradable material, extending from a point in a predetermined direction, each of said regions having trapezoidal cross sections taken along any planes perpendicular to the predetermined direction;

5 said first and second ascending regions having the trapezoidal cross sections of which base monotonically increases as being away from the point; and

 said descending region having the trapezoidal cross sections of which base monotonically decreases as being
10 away from the point;

 wherein said first and second ascending regions have the largest cross section having substantially the same size and shape to each other.

[Claim 19]

15 The medical lancet according to Claim 18, further comprising:

 at least one additional descending and ascending regions subsequently and integrally formed of biodegradable material and connected to said second ascending region,
20 extending in the predetermined direction;

 wherein each of said additional descending and ascending regions has the trapezoidal cross sections taken along any planes perpendicular to the predetermined direction, of which base monotonically increases and
25 decreases as being away from the point, respectively; and

wherein said first and second ascending regions have the largest cross section having substantially the same size and shape to each other.

[Claim 20]

5 The medical lancet according to Claim 18,
wherein the smallest cross section in the descending region has the base greater than a half of the base of the largest cross section in the ascending regions.

[Claim 21]

10 The medical lancet according to Claim 20,
wherein the smallest cross section in the descending region has the base greater than two-thirds of the base of the largest cross section in the ascending regions.

[Claim 22]

15 The medical lancet according to Claim 18,
wherein the largest cross sections in said first and second ascending regions are spaced away from each other by a gap greater than one micron.

[Claim 23]

20 The medical lancet according to Claim 18, further comprising:

 a constant region integrally formed of biodegradable material between said descending region and said second ascending region, having trapezoidal cross sections taken
25 along any planes perpendicular to the predetermined

direction, of which base is constant.

[Claim 24]

The medical lancet according to Claim 18,

wherein the base of the trapezoidal cross sections in
5 the first and second ascending regions are linearly
increased at first and second increasing rates,
respectively, and the first increasing rate falling within
a range between one-fourth and one of the second increasing
rate.

10 **[Claim 25]**

The medical lancet according to Claim 24,

wherein the first increasing rate is one-third of the
second increasing rate.

[Claim 26]

15 The medical lancet according to Claim 18, further
comprising:

a holding region of biodegradable material connected
to said second ascending region.

[Document Name] SPECIFICATION

[Title of the Invention] MEDICAL LANCET

[Technical field of the Invention]

[0001] The present invention relates to a medical lancet,
5 and in particular, to the medical lancet made of
biodegradable material such as poly lactic acid.

[Background of the Invention]

[0002] In general, when a patient has a hypodermic
injection, a needle is shot at an appropriate portion of
10 the body such as skin and muscle to inject medicine inside
the patient. Also, a diabetic uses a lancet to sample a
small amount of his or her blood by stinging it on any
suitable portions, e.g., at fingertip, for routine
measurement of the blood sugar. The patient having such a
15 needle or lancet pierced into the body, especially children,
sometimes suffers unendurable pain or uncomfortableness.
Also, a substantial area of cells around the tingled
portion may often be damaged, requiring some time to be
cured. Therefore, there has been long-felt desire to
20 develop a less invasive needle and lancet, minimizing the
pain (unpleasantness) experienced by the patient.

[0003] In fact, some of injection needles have been
proposed with a little pain to the patient. For example,
the Japanese Patent Publication Application JPA 10-57490,
25 explains the primary reason of the patient's pain that the

needle point "catches" the skin or flesh as the needle is penetrating. Also, it discloses a hypodermic needle with multi-beveled point geometry so as to reduce the pain.

[Patent Document] JPA 10-57490

5 [Disclosure of the Invention]

[Problem(s) to be solved by the Invention]

[0004] The present inventors has found the reason of the pain more precisely as described below, and made the invention based upon the knowledge. As the needle is
10 penetrating into the tissue such as skin and flesh of the patient, a contacting surface between an outer surface of the needle and the tissue of the patient is increased so that the frictional force therebetween becomes greater and the peripheral cells adjacent to the needle are drawn
15 inside deeply. To this end, the peripheral cells are extremely deformed by the physical stress due to the frictional force, and may often be burst away (collapsed) so that a pain-producing chemical mediator such as histamine and bradykinin is released within the tissue,
20 thereby hurting the patient. Also, the peripheral cells collapsed by the physical stress extend across the substantial region, which makes more painful and less healable. As described above, the conventional needle is highly invasive to pierce the tissue of the patient.

25 [0005] Also, the medical lancet is used to sampling a

drop of blood by stinging into the tissue at the appropriate portion of the patient's body. Thus, while there are possible drawbacks as the above-mentioned needles, it is highly desired to provide the medical lancet designed less invasive by minimizing the frictional stress to the peripheral tissue of the patient. According to the medical lancet of the present invention, it cuts the peripheral cells as few as possible and wedges away the intact tissues into the deep inside, as will be described herein in detail.

[0006] Therefore, one of the aspects of the present invention is to provide a less invasive (painful) medical lancet giving less pain to the patient.

[0007] Meanwhile, such a needle and lancet are disposed immediately after once used, to prevent various infections.

Since the conventional needle and lancet are generally made of metal, they are usually treated as industrial waste for landfill rather than as the burnable waste. However, it now raises a serious social problem because of the huge amount of the industrial waste and the risk of the infections thereby.

[0008] Therefore, another one of the aspects of the present invention is to provide the medical lancet integrally formed of biodegradable material such as Poly Lactic Acid, which can be degraded by micro-organisms once deposited in the soil.

[Means for solving the Problem(s)]

[0009] According to one aspect of the present invention, a medical lancet includes a first ascending region, a descending region, and a second ascending region subsequently and integrally formed of biodegradable material. Those regions extend from a point of the lancet in a predetermined direction, and each of the regions having triangular cross sections taken along any planes perpendicular to the predetermined direction. The first and second ascending regions have the triangular cross sections of which area monotonically increases as being away from the point. Also, the descending region has the triangular cross sections of which area monotonically decreases as being away from the point. The first and second ascending regions have the largest cross section having substantially the same size and shape to each other.

[0010] The medical lancet further includes at least one additional descending and ascending regions subsequently and integrally formed of biodegradable material and connected to the second ascending region, extending in the predetermined direction.

[0011] Also preferably, the smallest cross section in the descending region is similar to the largest cross section in the ascending regions, and the smallest cross section in the descending region has the area greater than

one-fourth of the area of the largest cross section in the ascending regions. More preferably, the smallest cross section in the descending region has the area greater than four-ninths of the area of the largest cross section in the ascending regions. Further, the largest cross sections in the first and second ascending regions are spaced away from each other by a gap greater than one micron.

[0012] The lancet further includes a constant region integrally formed of biodegradable material between the descending region and the second ascending region, having triangular cross sections taken along any planes perpendicular to the predetermined direction, of which area is constant.

[0013] Preferably, the area of the triangular cross sections in the first and second ascending regions are linearly increased at first and second increasing rates, respectively, and the first increasing rate falling within a range between one-sixteenth and one of the second increasing rate. More preferably, the first increasing rate is one-ninth of the second increasing rate.

[0014] The medical lancet may further include a holding region of biodegradable material connected to the second ascending region.

[0015] In one of the modifications of the present invention, the medical lancet further includes at least one

channel extending in the predetermined direction through at least one of the first and second ascending regions and descending region. Also, the holding region has at least one chamber in communication with the channel. The channel
5 has at least one opening. Preferably, the channel has at least two openings spaced away from each other by a predetermined gap. More preferably, a plurality of the channels are provided, and the holding region has a plurality of the chambers, each of the chambers being in
10 communication with corresponding one of the channels. Alternatively, the medical lancet further includes at least one groove extending in the predetermined direction through at least one of the first and second ascending regions and descending region.

15 [0016] Also, the medical lancet further includes a plurality of vertical cavities extending in a vertical direction perpendicular to the predetermined direction, and a seal membrane of biodegradable material for sealing the vertical cavities. The seal membrane has the thickness in
20 the vertical direction varying based upon the position of each of the vertical cavities.

[0017] According to the second aspect of the present invention, a medical lancet includes a first ascending region, a descending region, and a second ascending region
25 subsequently and integrally formed of biodegradable

material. Those regions extend from a point in a predetermined direction, each of the regions having trapezoidal cross sections taken along any planes perpendicular to the predetermined direction. The first and second ascending regions have the trapezoidal cross sections of which base monotonically increases as being away from the point. The descending region has the trapezoidal cross sections of which base monotonically decreases as being away from the point. The first and second ascending regions have the largest cross section having substantially the same size and shape to each other.

[0018] Preferably, the medical lancet further includes at least one additional descending and ascending regions subsequently and integrally formed of biodegradable material and connected to the second ascending region, extending in the predetermined direction. Each of the additional descending and ascending regions has the trapezoidal cross sections taken along any planes perpendicular to the predetermined direction, of which base monotonically increases and decreases as being away from the point, respectively. The ascending regions have the largest cross section have substantially the same size and shape to each other.

[0019] Preferably, the smallest cross section in the descending region has the base greater than a half of the

base of the largest cross section in the ascending regions. More preferably, the smallest cross section in the descending region has the base greater than two-thirds of the base of the largest cross section in the ascending regions. Further preferably, the largest cross sections in the first and second ascending regions are spaced away from each other by a gap greater than one micron. The medical lancet preferably includes a continuous curve between the descending region and the second ascending region for continuous connection therebetween.

[0020] Also, the medical lancet preferably further includes a constant region integrally formed of biodegradable material between the descending region and the second ascending region, having trapezoidal cross sections taken along any planes perpendicular to the predetermined direction, of which base is constant.

[0021] Preferably, the base of the trapezoidal cross sections in the first and second ascending regions are linearly increased at first and second increasing rates, respectively, and the first increasing rate falling within a range between one-fourth and one of the second increasing rate. More preferably, the first increasing rate is one-third of the second increasing rate.

[0022] The medical lancet may further include a holding region of biodegradable material connected to the second

ascending region.

[Advantage of the Invention]

[0023] One of the embodiments of the present invention is to provide a medical lancet which minimizes the pain
5 that the patient suffers and the damage to the pierced portion of the patient.

[0024] Another one of the embodiments of the present invention is to provide a medical lancet which can be disposed with no adverse effect on the ecology because it
10 is made of biodegradable material.

[Best Mode for Carrying Out the Invention]

[0025] Referring to the attached drawings, the details of embodiments according to the present invention will be described hereinafter. In those descriptions, although the
15 terminology indicating the directions (for example, "X-direction", "Y-direction", and "Z-direction") are conveniently used just for clear understandings, it should not be interpreted that those terminology limit the scope of the present invention. Also, the present invention
20 includes any modification and variation defined by the appendix claims without departing from the spirit and scope of the present invention, and is not interpreted as being limited by the particular embodiments that will be described hereinafter.

25 [0026] (Embodiment 1)

With reference to Figs. 1 to 4, the first embodiment of the medical lancet according to the present invention will be described herein. The medical lancet 1 is used to sample a drop of blood of a patient such as a diabetic for measurement of the blood sugar by stinging itself on the appropriate portion (e.g., fingertip) of the patient's body. As illustrated in Figs. 1 and 2, the lancet 1 extends along the X-direction and has a triangle cross section as taken along any Y-Z planes. The triangle cross section includes base, height, and area varying in accordance with the distance from a lancet point 11 or the position of the X-axis. Thus, the lancet 1 includes a first ascending region (first tissue incising region) 10 of which area is monotonically increased as being away from the point 11, a first descending region (first friction releasing region) 20 of which area is monotonically decreased as being away from the point 11, and a second ascending region (second tissue incising region) 30. A holding region 40 is connected to the second ascending region 30 of the lancet 1. According to the present invention, the lancet 1 is integrally formed of biodegradable material including for example, poly lactic acid, poly glycolic acid, poly caprolactone, collagen, amyllum, hyaluronic acid, alginic acid, chitin, chitosan, cellulose, gelatin, and the compound/composition/copolymer/

poly-microparticle thereof. Preferably, the holding region 40 is also integrally formed of the same material as that of the remaining regions. Therefore, the lancet 1 is degradable by micro-organisms so that once used it is easily deposited for landfill without raising any disposal problems unlike the metal lancet. Further, even if a portion of the lancet 1, for example when broken between the ascending and descending regions, is stuck within the patient body, the biodegradable material of the lancet 1 gives no harmful affect to the patient.

[0027] Next, referring to Figs. 2A to 2C, the structure of the regions 10, 20, 30 composing the lancet 1 will be described in more detail. Each of the first and second ascending regions 10, 30 and the first descending region 20 has an outer configuration registered with the respective portion of a particular rectangle pyramid.

[0028] The rectangle pyramid has a predetermined height (H) as shown in Figs. 2A and 2B, and a rhombic base 14 having first and second predetermined diagonals 12 (L_1), 13 (L_2), respectively. Preferably, the base is shaped as a square so that the first and second diagonals 12, 13 have the same length ($L_1 = L_2$). Further, the height of the rectangle pyramid has a half of the length of the first and second diagonals 12, 13 ($H = L_1/2 = L_2/2$), where the side surface (e.g., 17a, 17b) of the rectangle pyramid has a

shape of an equilateral triangle.

[0029] In particular, the first ascending region 10 has an outer configuration registered with a first portion of the particular rectangle pyramid taken along the Y-Z plane 51 as shown in Fig. 2B. The first descending region 20 has an outer configuration registered with a second portion of the rectangle pyramid taken along and between the Y-Z planes 51 and 52. Also, the second ascending region 30 has an outer configuration registered with a third portion of the rectangle pyramid taken along and between the Y-Z planes 52 and 53. As above, those regions 10, 20, 30 of the lancet 1 are integrally formed such that each of the regions includes a base surface arranged on the same X-Y plane and the second diagonal arranged on the same line along the x-axis. It should be noted that each of the rectangle pyramid configuring the respective region has substantial the same dimension.

[0030] In the lancet 1 so structured, the cross sections taken along any Y-Z planes are triangle and include a base, a height, and an area lineally increasing or decreasing depending upon the distance from a lancet point 11 or the position of the X-axis. In the above description, the increase and decrease in size of the regions 10, 20, 30 are explained as being linear functions of the distance from the lancet point 11 or the position along the x-axis.

However, it should be noted that the base, the height, and the area of the cross section in those regions may be defined as any non-linear functions such as a second or higher order functions which monotonically increases or decreases. Thus, the base, the height, and the area of the regions can be described by a linear or non-linear function monotonically increasing or decreasing as the parameter of the position along the x-axis.

[0031] According to the first embodiment of the present invention, the largest cross sections in the first and second ascending regions 10, 30 having the maximum area (i.e., the cross sections taken along the Y-Z planes 51 and 53) has triangular shapes, which are congruent with each other and similar to the smallest cross section in the first descending regions 20 having the minimum area (i.e., the cross section taken along the Y-Z plane 52).

[0032] Preferably, the lancet 1 of the first embodiment includes at least one additional descending region 20a, 20b and the ascending region 30a, 30b as shown in Figs. 3 and 4. In the additional ascending region 30a, 30b, the largest cross sections having the maximum area also have substantially the same shape and size as those of the other largest cross sections.

[0033] According to the lancet 1 illustrated in Figs. 1 to 3, when being penetrated deeply inside the tissue (skin

or flesh) of the patient's body, firstly, three of the sides (sharp ridge lines) 15a, 15b, 15c of the rectangle pyramid incise the peripheral cells around the point 11 of the first ascending region (first tissue incising region) 10. Then, the bottom surface 14 and the side surfaces 17a, 17b of the first ascending region 10 wedge away the intact (non-incised) tissues into the deep inside. Thus, the first incising region 10 cuts and advances into the peripheral cells in a smooth manner. As the first incising region 10 advances into the tissue, the frictional force is increased between the surfaces 14, 17a, 17b of the first incising region 10 and the peripheral tissue, so that the peripheral tissue may be drawn into the deep inside by the increased frictional force.

[0034] However, after the first incising region 10 sinks within the tissue, and as the lancet 1 is further penetrated inside the tissue, the frictional force between the peripheral tissue and first descending region (first friction releasing region) 20 is released since the first friction releasing region 20 has the cross section reducing or shrinking in size as being away from the point 11. Once the frictional force with the first incising region 10 is released, the peripheral tissue drawn inside by the frictional force will be reverted to the normal position by its elasticity. Thus, the peripheral tissue drawn by the

first incising region 10 is returned to the original state so that the physical stress applied to the peripheral cells is reduced or minimized. Therefore, when the lancet 1 is penetrated into the tissue by the half length ($L_1/2$) of the second diagonal of the rectangle pyramid, the peripheral cells drawn inside are released from the frictional force to be replaced, thereby preventing the peripheral cells from being collapsed. This minimizes the pain-producing chemical mediator to give substantially less pain to the patient, and avoids the unrecoverable damage (collapse) of the peripheral cells across a substantial area around the point 11.

[0035] Again, after the first releasing region 20 sinks within the tissue, and as the lancet 1 further advances deeply inside the tissue, three of the sides 35a, 35b, 35c of the second ascending region 30 incise substantially the same peripheral cells as the first ascending region cuts. Also, the bottom surface and the side surfaces 37a, 37b of the second ascending region 30 get the intact (non-incised) tissues out of the way, avoiding the unrecoverable damage of the peripheral cells. As above, since the largest cross sections of the first and second ascending regions 10, 30 are congruent with each other having substantially the same size and shape, the number of the incised cells can be minimized when the lancet 1 is penetrating inside the

patient's body.

[0036] Thus, the penetrating process of the lancet 1 according to the present invention is achieved by repeatedly incising the peripheral cells and wedging away the intact tissues by the ascending regions 10, 30, and releasing the frictional force with the peripheral cells by the descending region 20 to replace thereof in its original position. Also, the present invention provides a non-invasive lancet 1 minimizing the pain to the patient by returning the peripheral cells across the substantial area back to the original position and by avoiding the damage of the peripheral cells.

[0037] Meanwhile, although depending upon the portion of patient's body, one of the peripheral cells has a size of about 10 microns in general, and in particular, the microcyte in the micro-vessel has the size of 5 microns. The rectangle pyramid is designed so as to have the first and second diagonals (L_1 , L_2) and the height (H) of about 85 to 180 microns and about 42.5 to 90 microns, respectively. Thus, the largest cross section in the ascending regions 10, 30 has a triangle shape having a base of about 85 to 180 microns and a height of about 42.5 to 90 microns.

[0038] When the base and the height of the smallest cross section taken along the Y-Z plane are

approximately less than a half of those of the largest cross section taken along the Y-Z planes 51, 53, the medical lancet 1 has insufficient strength so that it tends to break off between the descending region 20 and the second ascending region 30. Thus, if the base and the height of the smallest cross section are approximately less than about 42.5 to 90 microns and about 21.2 to 45 microns, respectively, then the lancet 1 is easily broken off. Therefore, the lancet 1 of the embodiment is designed such that the base and the height of the smallest cross section are approximately greater than a half of those of the largest cross section, and thus the smallest cross section is approximately greater than a quarter (square of a half) of the largest cross section. More preferably, the lancet 1 is designed such that the base and the height of the smallest cross section is approximately greater than two-thirds ($2/3$) of those of the largest cross section, and thus the smallest cross section is approximately greater than four-ninths ($4/9$: square of $2/3$) of the largest cross section. This realizes a stubborn and reliable lancet 1 without breaking off and/or bending so as to secure piercing into the patient's body.

[0039] Also, the descending region 20 should have the size for releasing the frictional stress of the peripheral cells, i.e., the size of at least one cell, thus as

illustrated in Fig. 2A, the gap (D) between the adjacent largest cross sections taken along the Y-Z planes 51 and 53 is designed to have at least one (1) micron and preferably five (5) microns.

5 [0040] As above, according to the medical lancet 1 of Figs. 1-4, the side surfaces 21, 37 of the descending region 20 and second ascending region 30 are described as substantially flat planes so that an angled portion (discontinuous portion) is formed therebetween. Contrary,
10 as illustrated in Fig. 5, the lancet 1 may have a continuous curved portion 58 smoothly connecting the side surfaces 21, 37 of the descending region 20 and second ascending region 30. The continuous curved portion 58 makes the lancet 1 even stiffer against the stress
15 otherwise concentrated on that portion. Also, it should be noted that although the cross section of the holding region 40 taken along any Y-Z planes is illustrated to be a triangle, it can be a rectangle or any other shapes for appropriate fit to an external holder mechanism (not shown).

20 [0041] (Embodiment 2)

With reference to Figs. 6 to 9, the second embodiment of the medical lancet according to the present invention will be described herein. The medical lancet 2 of the second embodiment is similar to the medical lancet 1
25 of the first embodiment except that it additionally

includes a constant region (reinforcing region). Therefore, the duplicated description in detail for the common features will be eliminated.

[0042] As above, the medical lancet 2 of the second embodiment has a constant region (reinforcing region) 60 for reinforcing the strength of the lancet 2 between the first descending region 20 and the second ascending region 30 as shown in Figs. 6 and 7. The constant region 60 has an outer configuration of a triangular prism having a size of X-, Y-, and Z-directions (l_x , l_y , l_z) with a triangular base 61 that is substantially the same shape and size as the smallest cross section in the descending region 20. Thus, the constant region 60 has a triangle cross section having a base (l_y) and a height (l_z) as taken along any Y-Z planes.

[0043] According to the second embodiment, similar to the first embodiment, the base and the height (l_y , l_z) of the constant region 60 are designed to be approximately greater than a half, preferably a two-thirds (2/3) of those of the largest cross section (L_1 , H), respectively, i.e.,

$$l_y \geq L_1/2, l_z \geq H/2; \text{ and preferably,}$$

$$l_y \geq 2L_1/3, l_z \geq 2H/3.$$

This design reinforces the strength between the descending region 20 and the second ascending region 30 so as to realize a more stubborn lancet 2.

[0044] Also as the first embodiment, the lancet 2 of the second embodiment may include at least one additional descending region 20a, 20b, the constant region 60a, 60b, and the ascending region 30a, 30b, as illustrated in Figs. 8 and 9.

[0045] (Embodiment 3)

With reference to Fig. 10, the third embodiment of the medical lancet according to the present invention will be described herein. The medical lancet 3 of the third embodiment is similar to the medical lancet 1 of the first embodiment except that the lancet point is formed sharper than that of the first embodiment. Therefore, the duplicated description in detail for the common features will be eliminated.

[0046] In Figs. 10B and 10C, the first and second ascending region 10, 30 are designed so as to have the triangular cross section taken along any Y-Z planes, of which height and base are increased linearly as being away from the point 11 with gradients (increasing rates) indicated by a solid line 55 and a one-dotted line 54, respectively. Also, the increasing rate (k) of the height and base of the first ascending region 10 indicated by the solid line 55 varies from an increasing rate (k_1) indicated by one imaginary line 56 to another increasing rate (k_2) indicated by another imaginary line 57, i.e.,

$$k_2 \leq k \leq k_1.$$

The imaginary line 56 is parallel to the one-dotted line 54 of the second ascending region 30 having the increasing rate (k_0), and the other imaginary line 57 is approximately
 5 a quarter of the increasing rate (k_0), i.e.,

$$k_0/4 \leq k \leq k_0.$$

Preferably, the increasing rate (k) of the height and the base of the first ascending region 10 is set to one-third ($1/3$) of the increasing rate (k_0) of the second ascending
 10 region 30, i.e.,

$$k = k_0/3.$$

[0047] Therefore, when the increasing rate of the cross section (area) of the second ascending region 30 is represented by (K_0), the increasing rate (K) of the cross
 15 section (area) of the first ascending region 10 falls within a range between one-sixteenth ($1/16$; square of a quarter) and one of the second ascending region 30, i.e.,

$$K_0/16 \leq K \leq K_0.$$

Preferably, the increasing rate (K) of the cross section of
 20 the first ascending region 10 is set to one-ninth ($1/9$; square of $1/3$) of the increasing rate (K_0) of the second ascending region 30, i.e.,

$$K = K_0/9.$$

For example, suppose if the rectangle pyramid defining the
 25 outer configuration of the ascending and descending regions

includes the first and second diagonals (L_1 , L_2) of the same length and the height that is the same as a half of the diagonals, i.e., $H = L_1/2 = L_2/2$. Then, the first ascending region has the length in the X-direction varying
5 between $L_1/2$ to $2L_1$, preferably $3L_1/2$, and also the point angle (θ) indicated in Fig. 10B varies between about 14 degree to 45 degrees, preferably is about 18.3 degree.

[0048] According to the lancet 3 of the third embodiment, the height and the base of the cross section in the first
10 ascending region 10 are more moderately increased than those in the second ascending region 30 so that lancet point 11 of the embodiment is sharper and more elongated. This contributes the lancet 3 of the third embodiment to be penetrated more smoothly into the deep inside with less
15 resistance, thereby further reducing the pain to the patient.

[0049] As persons skilled in the art can easily conceive, the medical lancet of foregoing embodiments can be manufactured, for example, by use of ROMONANO α -0iA®
20 commercially available from a FUNAC Ltd. in Yamanashi Pref., JAPAN.

[0050] (Modification 1)

With reference to Figs. 11 to 13, the first modification of the medical lancet will be described herein.
25 The medical lancet 101 of the first modification is similar

to the medical lancets 1, 2, 3 of the first to third embodiments except that at least one channel and chamber are provided within the lancet. Therefore, the duplicated description in detail for the common features will be eliminated.

[0051] The lancet 101 of the first modification includes at least one channel 71 extending through the incising regions 10, 30 and the releasing region 20 of the lancet 101 as illustrated in Fig. 11A. Preferably, the holding region 40 includes at least one chamber 81 in communication with the channel 71, which has the rectangular cross section taken along any Y-Z planes as shown in Fig. 11C. Also, the lancet 101 has at least one opening 72 close to the point 11, extending through any appropriate surfaces such as the bottom surface 73 of the descending region 20.

[0052] The lancet 101 having the channel 71 and the chamber 81 can be used in various applications. For example, a pair of electrodes (not shown) spaced away from each other may be arranged within the channel 71 and also a bio-sensor (not shown) such as a Micro Total Analysis System (μ -TAS) may be received in the chamber 81. When the lancet 101 so structured is penetrated into the body, the μ -TAS can readily analyze the component of the blood plasma coming into the opening 72.

[0053] Instead of the channel 71 and the opening 72 as

shown in Fig. 11, the lancet 101 may include a groove 74 extending along the X-direction on the bottom surface 73 as illustrated in Fig. 12. Also, the lancet 101 may include a pair of electrodes arranged within the channel 71 and also
5 a bio-sensor received in the chamber 81 to analyze the desired component of the blood.

[0054] Alternatively, the lancet 101 of the modification may include a plurality of channels extending in the X-direction and a plurality of chambers in the holding region
10 40, each separately communicating with corresponding one of the chambers (two channels 75, 76 and two chambers 82, 83 are shown in Fig. 13). Also, a plurality of openings 77a-77c, and 78a-78c are formed adjacent the point 11, for example, extending through the side surfaces of the regions
15 10, 20, 30 as illustrated in Figs. 13A and 13B. Each of the channels 75, 76 may receive the independent electrode pairs and also each of the chambers 82, 83 may include a different bio-sensors therein for analyzing a plurality types of blood components. Alternatively, plural kinds of
20 medicaments may be reserved within the chambers 82, 83 for gradually releasing the medicaments into the patient's body through the openings 77, 78. If desired, each of the openings 77, 78 may be sealed by a sheet (not shown) made of biodegradable material same as that of the lancet 101 so
25 as to allow the medicaments to be gradually released a

predetermined time after the lancet 101 is stuck in the tissue of the patient. In addition, the thickness of the sheets may be changed depending upon the channels 75, 76 so that the timing for gradual release of the medicaments can be controlled.

[0055] More preferably, the adjacent openings 77, 78 are spaced away from each other by a predetermined gap. One example is where each of the electrodes is assembled to be extruded through the respective one of openings 77, 78, then the distance between the electrodes is defined exactly, allowing the fluid between the electrodes to be analyzed in a more precise manner. Also, another example is where a pair of fiber optics are extruded through the openings 77b and 77c so that beams from each of the fiber optics intersect each other, then the fluid at the intersection of the beam can be inspected more accurately due to the precisely defined geometry.

[0056] (Modification 2)

With reference to Figs. 14 and 15, the second modification of the medical lancet will be described herein. The medical lancet 102 of the second modification is similar to the medical lancets 1, 2, 3 of the first to third embodiments except that a vertical cavity and a seal membrane for sealing the vertical cavity are provided within the lancet. Therefore, the duplicated description

in detail for the common features will be eliminated.

[0057] As above, the medical lancet 102 of the second modification includes at least one vertical cavity (four vertical cavities 91a-91d are shown in Figs. 14A, 14B) extending in a vertical direction (Z-direction) and a seal membrane 92 for sealing the vertical cavity. The vertical cavity 91 receives a micro-particle or fluid containing medicament therein. Also, the seal membrane 92 is made of biodegradable material so that in conjunction with the lancet 102, it seals the vertical cavity to secure the medicament therein without slipping off from the vertical cavity 91.

[0058] When the lancet 102 is penetrated and held permanently within the patient body, especially, the biodegradable material especially composing the seal membrane 92 is gently degraded so that medicament contained within the micro-particle or the like received in the vertical cavity 91 is gradually released. Preferably, in case where a plurality of cavities for different medicaments are provided, the seal membrane 92 is designed such that it has the thickness in the Z-direction varying based upon the position of the vertical cavities 91a-91d. In one example shown in Fig. 15A, the seal membrane 92 has the thickness tapered towards the point 11, and in another example shown in Fig. 15B, the seal membrane 92 is stepped

such that it is the thinnest at the cavity 91a, and the second thinnest at the cavity 91b, and the thickest at the last cavity 91d. This structure controls the timing for gradual release of the medicament received in the vertical cavities 91a-91d.

[0059] It should be noted that as persons skilled in the art easily conceive and practice, the channel 71, the chamber 81, the openings 77, 78, and the vertical cavities 91a-91d of the first and second modifications are formed with use of a laser device such as an excimer laser emitting laser beam having adjustable power.

[0060] (Embodiment 4)

With reference to Figs. 16 to 18, the fourth embodiment of the medical lancet will be described herein.

The medical lancet 4 of the fourth embodiment is similar to the medical lancet 1 of the first embodiment except that while the latter has the triangular cross sections taken along any Y-Z planes, the former has the trapezoidal cross sections taken along any Y-Z planes. Therefore, the duplicated description in detail for the common features will be eliminated.

[0061] As clearly understood by comparing Figs. 3 and 10 of the first embodiment with Fig. 16 of the fourth embodiment, the lancet 4 of the present embodiment has the trapezoidal, rather than triangular, cross sections taken

along any Y-Z planes. The trapezoid has the base (i.e., each of the upper and lower bases) varying in accordance with the distance from the lancet point 11 or the position in the X-direction, and the height (H) that is constant.

5 Thus, the lancet 4 of the present embodiment includes first and second ascending regions (first and second tissue incising regions) 10, 30, of which trapezoidal cross sections taken along any Y-Z planes has the base monotonically increasing as being away from the point 11, a
10 first descending region (first friction releasing region) 20 of which trapezoidal cross sections taken along any Y-Z planes has the base monotonically decreasing as being away from the point 11. Also, the holding region 40 is connected with the subsequent ascending region 20. Since
15 the lancet of the present invention is integrally made of the aforementioned biodegradable material, it can be disposed without any environment problems, and also be retained in the patient's body.

[0062] According to the fourth embodiment, the first and
20 second ascending regions 10, 30 have the largest trapezoidal cross section, of which bases have substantially the length same as each other. Also, although in view of incising the peripheral cells or tissue, the height (H) of the trapezoidal cross section is
25 preferably short (the lancet 4 is thin), however, the

height has to be taller than a predetermined dimension for ensuring sufficient strength of the lancet 4. In particular, the lancet 4 of the embodiment preferably has the thickness (H) greater than about one-eighth of the base of the largest cross section, i.e., the first diagonal (L_1) of the rectangular pyramid (i.e., $H \leq L_1/8$).

[0063] In Figs. 17A-17C and 18A-18C, the base of the smallest cross section is preferably greater than a half, and more preferably greater than about two-thirds of the largest cross section. Also, like the first embodiment, the largest cross sections in first and second ascending regions 10, 30 adjacent to each other is spaced away preferably by a predetermined gap (D) of at least 1 micron.

[0064] Further, similar to the first embodiment, the lancet 4 of the fourth embodiment may include at least one additional descending region and ascending region integrally formed with the second ascending region 20. Also, similar to the second embodiment, the lancet 4 of the fourth embodiment may include at least one additional constant (reinforcing) region having the cross section of substantially the constant area, which is formed between the descending and ascending regions.

[0065] In addition, similar to the third embodiment, the first ascending region 10 of the lancet 4 is designed sharper such that the base of the trapezoidal cross section

increases gently. The increasing rate of the base of the trapezoidal cross section in the first ascending region 10 falls within a range between about one-fourth and one of the increasing rate of the trapezoidal cross section in the second ascending region 30. Thus, the lancet 4 of the fourth embodiment is sharp so that it can easily be penetrated into the tissue, minimizing the pain to the patient.

[Brief Description of Drawings]

10 [0066] Fig. 1 is a perspective view of a medical lancet according to the first embodiment of the present invention.

Figs. 2A-2C are front elevational, side, and top views of the medical lancet shown in Fig. 1, respectively.

15 Fig. 3 is a perspective view of another medical lancet according to the first embodiment.

Figs. 4A-4C are front elevational, side, and top views of the medical lancet shown in Fig. 3, respectively.

Figs. 5A-5C are perspective, side, and top views of another medical lancet according to the first embodiment.

20 Fig. 6 is a perspective view of a medical lancet according to the second embodiment of the present invention.

Figs. 7A-7C are front elevational, side, and top views of the medical lancet shown in Fig. 6, respectively.

25 Fig. 8 is a perspective view of another medical lancet according to the second embodiment.

Figs. 9A-9C are front elevational, side, and top views of the medical lancet shown in Fig. 8, respectively.

Figs. 10A-10C are perspective, side, and top views of a medical lancet according to the third embodiment
5 of the present invention.

Figs. 11A-11C are side, top, and rear elevational views of the medical lancet of the first modification.

Figs. 12A and 12B are side and bottom views of another medical lancet of the first modification.

10 Figs. 13A and 13B are side and top views of further another medical lancet of the first modification.

Figs. 14A and 14B are side and bottom views of a medical lancet of the second modification.

15 Figs. 15A and 15B are side views of another medical lancet of the second modification.

Figs. 16A and 16B are perspective views of a medical lancet according to the fourth embodiment of the present invention.

20 Fig. 17A-17C are front elevational, side, and top views of the medical lancet shown in Fig. 15A, respectively.

Figs. 18A-18C are front elevational, side, and top views of the medical lancet shown in Fig. 15B, respectively.

[Brief Description of Reference Numerals]

25 1, 2, 3, 4, 101, 102: medical lancet

- 10: first ascending region (first tissue incising region)
- 11: tip
- 12: first diagonal
- 13: second diagonal
- 5 14: base
- 15a, 15b, 16: side (sharp ridge lines)
- 17a, 17b: side surface
- 20: descending region (friction releasing region)
- 21: side surface
- 10 30: second ascending region (second tissue incising region)
- 37a, 37b: side surface
- 40: holding region
- 51, 52, 53: Y-Z plane
- 60a, 60b: constant region
- 15 71, 75, 76: channel
- 72: opening
- 73: base
- 74: groove
- 77, 78: opening
- 20 81, 82, 83: chamber
- 91: vertical cavity
- 92: seal membrane

[Document Name] ABSTRACT

[Abstract]

[Problem(s) of the Invention]

5 The present invention is to provide a medical lancet which, when pierced into the patient, minimizes the pain that the patient suffers and the damage to the pierced portion of the patient.

[Means for Solving the Problem(s)]

10 The medical lancet of the present invention comprises a first ascending region, a descending region, and a second ascending region subsequently and integrally formed of biodegradable material, extending from a point in a predetermined direction, each of the regions having triangular cross sections taken along any planes
15 perpendicular to the predetermined direction. The first and second ascending regions have the triangular cross sections of which area monotonically increases as being away from the point. The descending region has the triangular cross sections of which area monotonically
20 decreases as being away from the point. The first and second ascending regions have the largest cross section having substantially the same size and shape to each other.



Fig.1

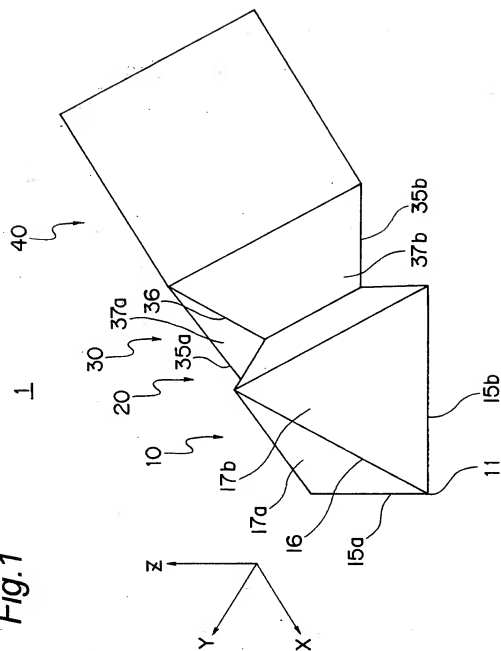


Fig.2A

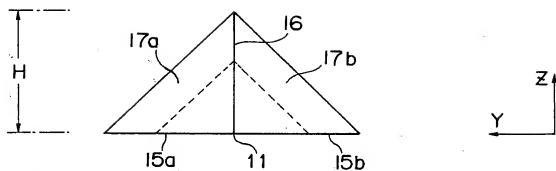


Fig.2B

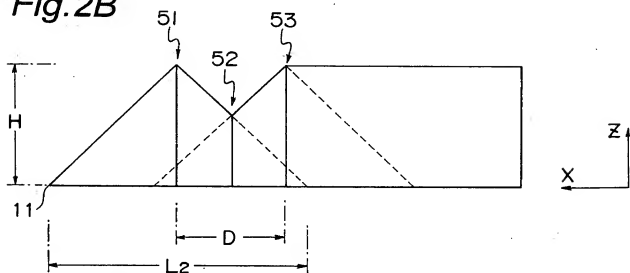


Fig.2C

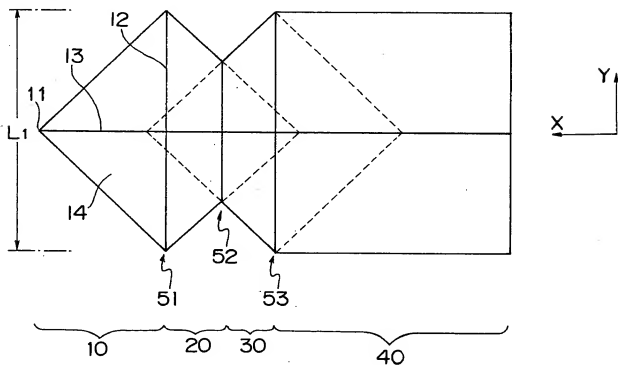


Fig.3

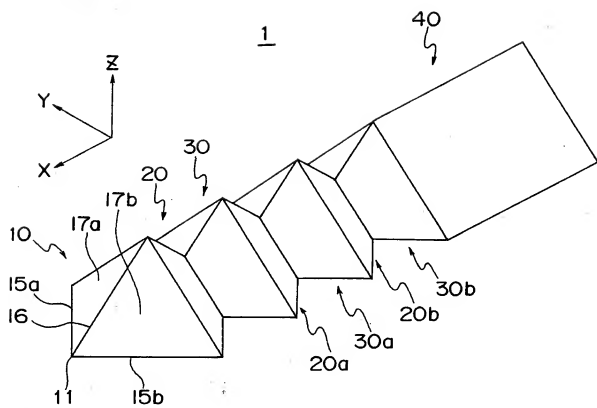


Fig. 4A

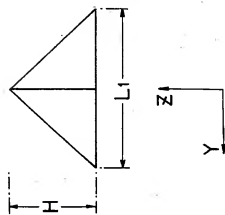


Fig. 4B

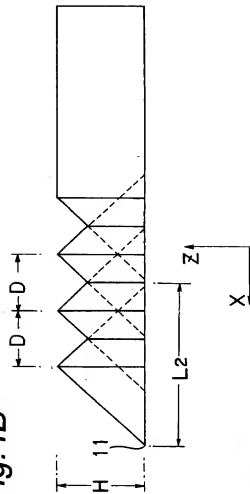


Fig. 4C

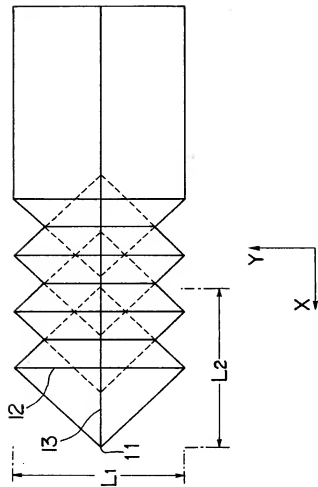


Fig. 5A

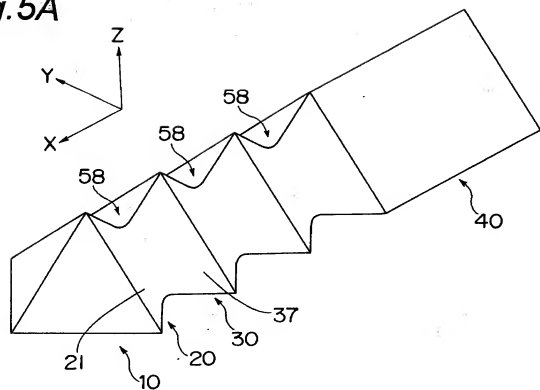


Fig. 5B

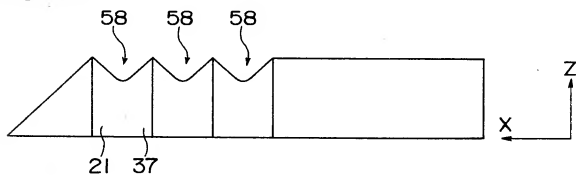


Fig. 5C

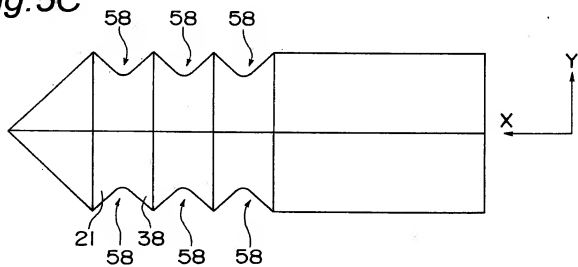


Fig.6

2

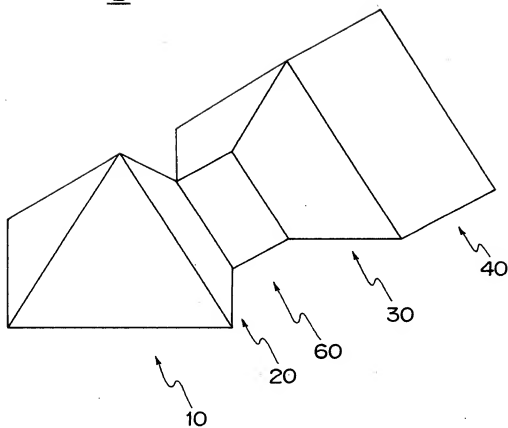
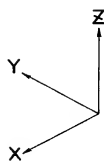


Fig. 7A

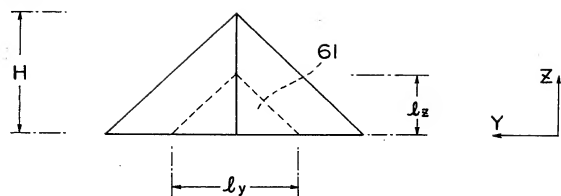


Fig. 7B

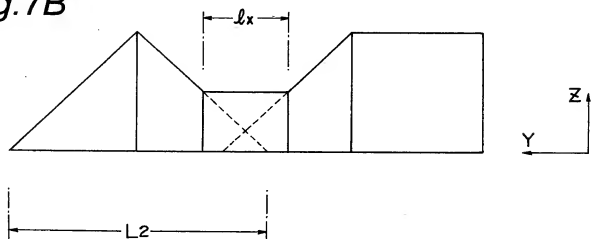


Fig. 7C

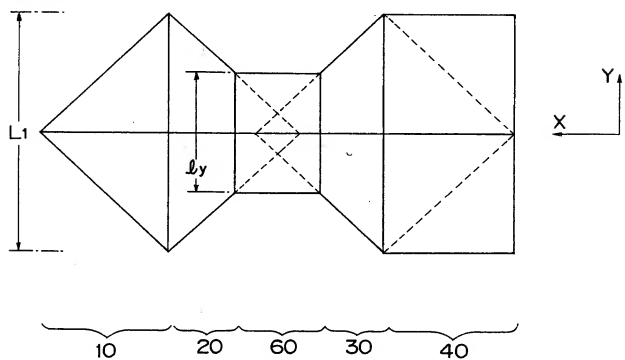


Fig. 8

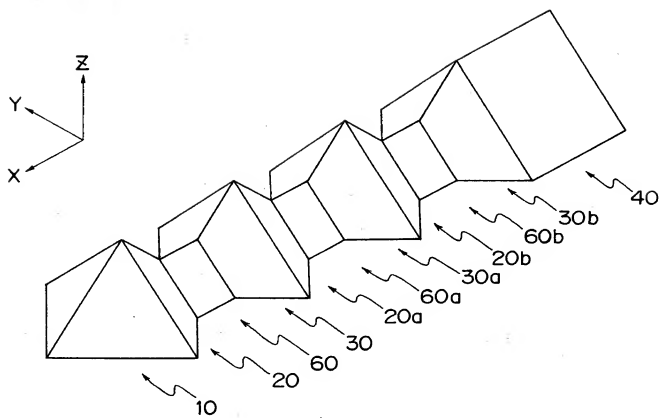


Fig. 9A

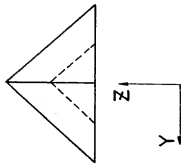


Fig. 9B

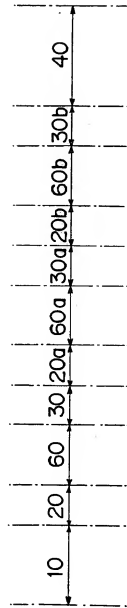
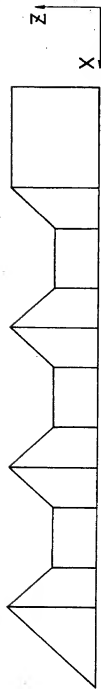


Fig. 9C

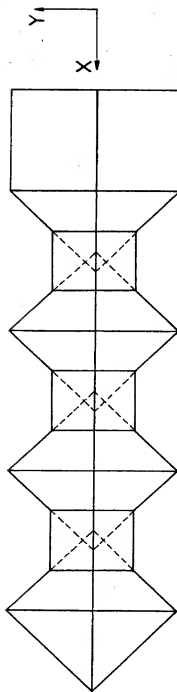


Fig. 10A

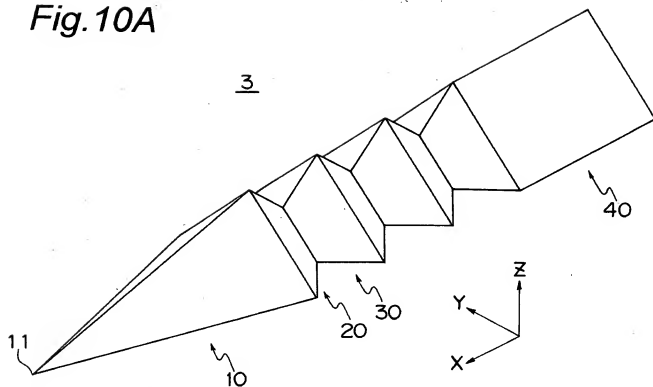


Fig. 10B

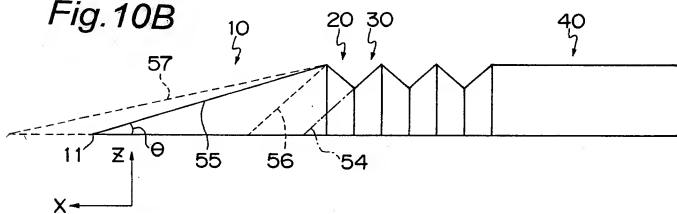
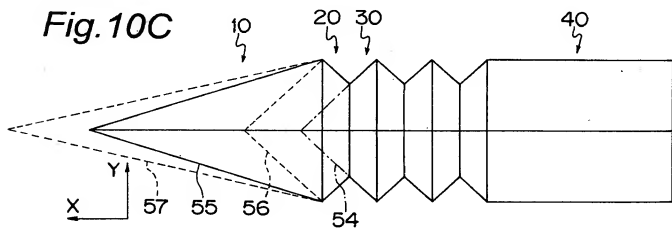


Fig. 10C



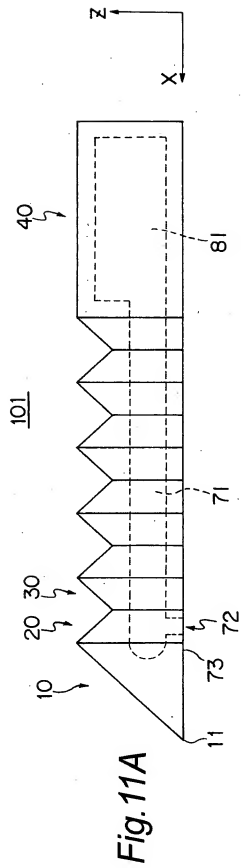
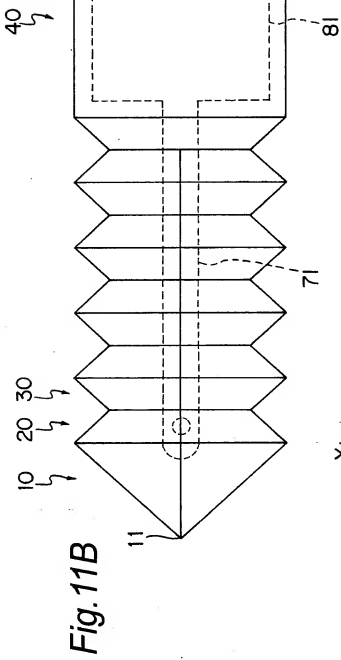
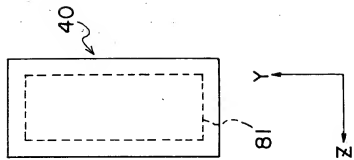


Fig. 11C



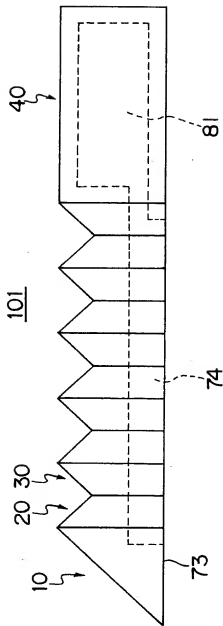


Fig. 12A

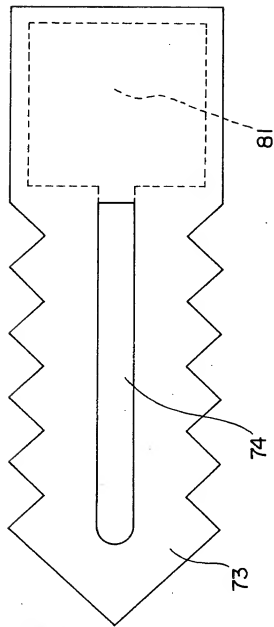


Fig. 12B

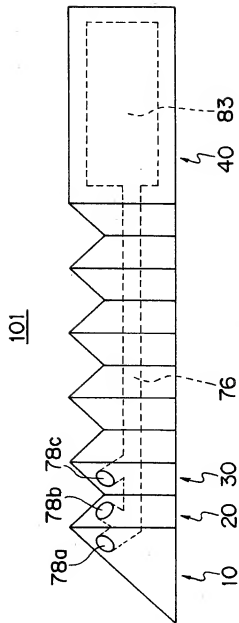


Fig. 13A

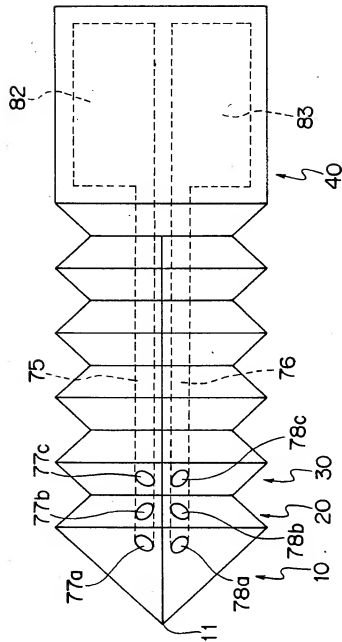


Fig. 13B

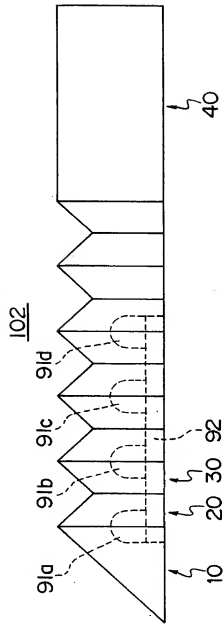


Fig. 14A

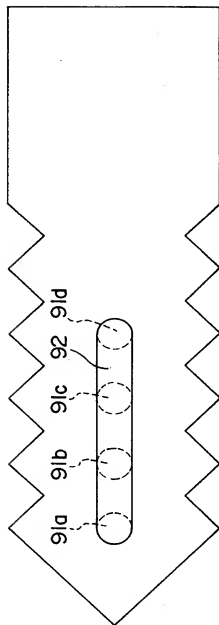


Fig. 14B

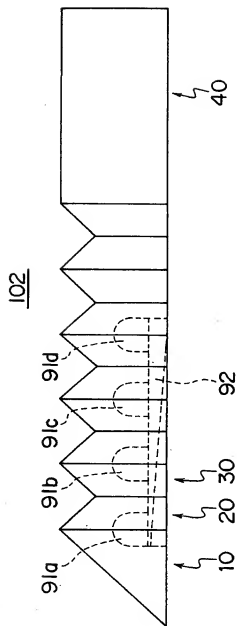


Fig. 15A

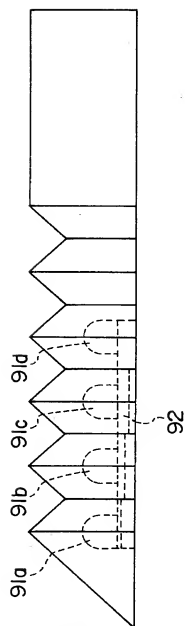


Fig. 15B

Fig.16A

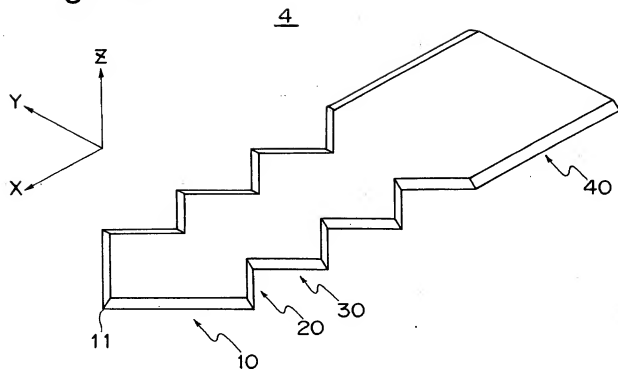


Fig.16B

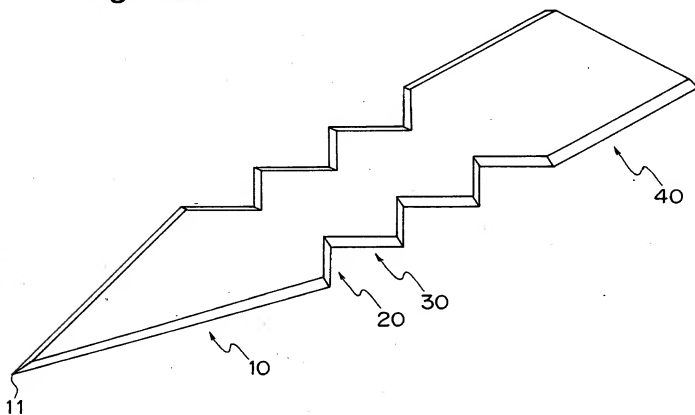


Fig.17A

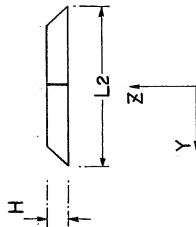


Fig.17B

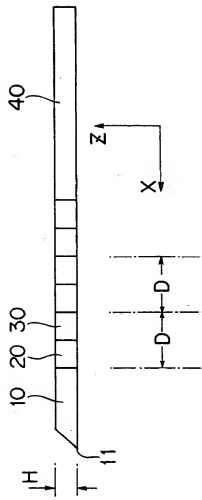


Fig.17C

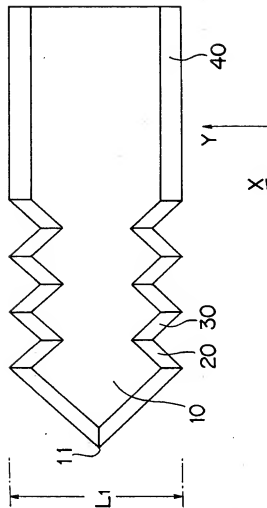


Fig.18A

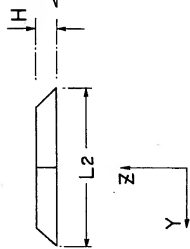


Fig.18B

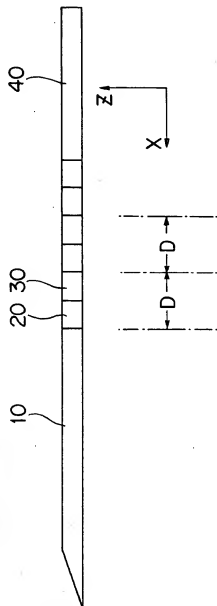


Fig.18C

